MAY 1 0 2002

K020763

510(k) Summary of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

Submitter name, Address, and Contact

Lin-Zhi International, Inc.
2391 Zanker Road, Suite 340
San Jose, CA 95131-1124
Phone: (408) 944-0360
Fax: (408) 944-0359

Contact: Chiu Chin Chang, Ph.D.
VP, R&D

Device Name and Classification

Classification Name:	Enzyme Immunoassay, Cocaine and Cocaine Metabolites, Class II, DIO (91 Toxicology), 21CFR 862.3250
Common Name:	Homogeneous enzyme immunoassay for the determination of benzoylecgonine (cocaine metabolite) level in urine.
Proprietary Name:	None

Legally Marketed Predicate Device(s)

Lin-Zhi International, Inc.' Cocaine Metabolite Enzyme Immunoassay is substantially equivalent to the Cocaine Metabolite Enzyme Immunoassay (By DRI/Microgenics Corp.), cleared under premarket notification K960187.

LZI's Cocaine Metabolite Enzyme Immunoassay is identical or similar to its predicate in terms of intended use, method principle, device components, and clinical performance.

Device Description

LZI's Cocaine Metabolite Enzyme Immunoassay is a ready-to-use, liquid reagent, homogeneous enzyme immunoassay. The assay uses specific antibody that can detect benzoylecgonine (cocaine metabolite) in human urine with minimal cross-reactivity to various, common prescription drugs and abused drugs.

The assay is based on competition between benzoylecgonine labeled with glucose-6-phosphate dehydrogenase (G6PDH) enzyme, and free drug from the urine sample for a fixed amount of specific antibody. In the absence of free drug from the urine sample the specific antibody binds to the drug labeled with G6PDH enzyme causing a decrease in enzyme activity. The G6PDH enzyme activity is determined spectrophotometrically at 340 nm by measuring its ability to convert nicotinamide adenine dinucleotide (NAD) to NADH.

Intended Use

The Cocaine Metabolite Enzyme Immunoassay is a homogeneous enzyme immunoassay with a 300 ng/mL cutoff. The assay is intended for use in the qualitative and semi-quantitative analyses of benzoylecgonine (cocaine metabolite) in human urine.

Comparison to Predicate Device

LZI's Cocaine Metabolite Enzyme Immunoassay is substantially equivalent to other products in commercially distribution intended for similar use. Most notably it is substantially equivalent to the currently, commercially marketed Cocaine Metabolite Enzyme Immunoassay (K960187) by Diagnostic Reagents, Inc. (DRI, now Microgenics Corporation)

The following table compares LZI's Cocaine Metabolite Enzyme Immunoassay with the predicate device, DRI's Cocaine Metabolite Enzyme Immunoassay. Specific data on the performance of the test have been incorporated into the proposed product insert (Attachment A). Product inserts for the predicate device and two other commercial products of similar intended use are provided in the Attachment C.

Similarities:

- Both assays are for qualitative and semi-quantitative determination of benzoylecgonine (cocaine metabolite) in human urine.
- Both assays use the same method principle, and device components.
- Both assays use 300 ng/mL as cutoff level per recommendations of The Substance Abuse and Metal Health Services Administration (SAMHSA).

Differences:

- Assay range for the DRI's assay is 0 to 1000* ng/mL; LZI's assay range is 0 to 3000 ng/mL.
- LZI's Cocaine Metabolite Enzyme Immunoassay uses 5 calibrators for the semi-quantitative analysis of benzoylecgonine (cocaine metabolite) concentration in urine. DRI's Cocaine Metabolite EIA used 3 calibrators previously. A total of 5 calibrators are available now from DRI.

* Previously DRI assay range was also 0 to 3000 ng/mL as indicated in its product insert of 03/98.

(Comparison to Predicate Device, continued)

Performance Characteristics

Feature	DRI's Cocaine Metabolite EIA				LZI's Cocaine Metabolite EIA			
Within Run Precision:								
Qualitative:		Mean Rate	SD	% CV		Mean Rate	SD	% CV
	Negative	302	2.0	0.7	Negative	243.7	0.9	0.37
	225 ng/mL	341	2.5	0.7	225 ng/mL	356.8	1.8	0.50
	300 ng/mL	354	3.4	0.9	300 ng/mL	380.2	1.8	0.48
	375 ng/mL	374	2.4	0.6	375 ng/mL	397.3	2.2	0.56
	*3000 ng/mL	442	3.6	0.8	3000 ng/mL	488.4	1.8	0.36
Semi-quantitative:	No data available.					Mean Conc.	SD	% CV
					225 ng/mL	226.2	3.3	1.45
					300 ng/mL	303.4	4.6	1.53
					375 ng/mL	370.7	5.1	1.37
Run-To-Run Precision:								
Qualitative:		Mean Rate	SD	% CV		Mean Rate	SD	% CV
	Negative	302	3.9	1.3	Negative	243.1	0.9	0.36
	225 ng/mL	342	3.9	1.1	225 ng/mL	354.8	2.4	0.67
	300 ng/mL	354	4.9	1.4	300 ng/mL	377.0	3.5	0.93
	375 ng/mL	374	5.1	1.4	375 ng/mL	394.6	2.1	0.53
	*3000 ng/mL	443	5.2	1.2	3000 ng/mL	486.0	2.4	0.49
Semi-quantitative:	No data available.					Mean Conc.	SD	% CV
					225 ng/mL	226.7	3.2	1.41
					300 ng/mL	307.9	5.1	1.65
					375 ng/mL	376.8	6.9	1.83
Sensitivity:	40 ng/mL				4 ng/mL			
Accuracy:	Vs. a commercial EIA				Vs. DRI's Cocaine Metabolite EIA			
Sensitivity:	100 %				100 %			
Specificity:	100 %				100 %			
Analytical Recovery:								
Qualitative:	No data available				100 % accuracy on positive vs. negative tests			
Semi-quantitative:	No data available				Quantitate within ±10% of the nominal concentration between 30 ng/mL and 2100 ng/mL. Average 100.6 % recovery at 225 ng/mL level (Cutoff -25%) Average 97.3 % recovery at 375 ng/mL level (Cutoff + 25%)			
Specificity:	See attached DRI's Cocaine Metabolite EIA package insert				Comparable to the predicate device.			

*Data from 03/98 package insert. The assay range for DRI assay now is 0 to 1000 ng/mL.

Conclusion

LZI's Cocaine Metabolite Enzyme Immunoassay was evaluated for several performance characteristics including precision, sensitivity, accuracy, analytical recovery, and specificity. All the studies showed acceptable results when compared to the predicate device.

We trust the information provided in this Premarket Notification [510(k)] submission will support a determination of substantial equivalence of the LZI's Cocaine Metabolite Enzyme Immunoassay to other cocaine metabolite test systems currently marketed in the United States.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 1 0 2002

Chiu Chin Chang, Ph.D.
VP, R&D
Lin-Zhi International, Inc.
2391 Zanker Road, Suite 340
San Jose, CA 95131-1124

Re: k020763
Trade/Device Name: Cocaine Metabolite Enzyme Immunoassay
Regulation Number: 21 CFR 862.3250
Regulation Name: Cocaine and cocaine metabolite test system
Regulatory Class: Class II
Product Code: DIO
Dated: April 15, 2002
Received: April 24, 2002

Dear Dr. Chang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Premarket Notification

Indications for Use Statement

510(k) Number (if known): K020763

Device Name: Cocaine Metabolite Enzyme Immunoassay

Indications for Use:

The Cocaine Metabolite Enzyme Immunoassay is a homogeneous enzyme immunoassay with a 300 ng/mL cutoff. The assay is intended for use in the qualitative and semi-quantitative analyses of benzoylecgonine (cocaine metabolite) in human urine.

The Cocaine Metabolite Enzyme Immunoassay provides only a preliminary analytical test result. A more specific alternative chemical method must be used to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgement should be applied to any drug-of-abuse test result, particularly when preliminary positive results are used.

Joan Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K020763

Concurrence of CDRH, Office of Device Evaluation (ODE)

✓

Prescription Use **OR** **Over-The-Counter Use**
(Per 21 CFR 801.109)

(Optional Format 1-2-96)